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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,966	10/02/2001	John A. Stolk	210121.484C6	3194

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EXAMINER

ZEMAN, MARY K

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/14/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,966

Applicant(s)

STOLK ET AL.

Examiner

Mary K Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group XX, claim 14 and SEQ ID NO: 199, 210, 211 and 214 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-13 and 15-18 have been canceled, and claims 19-21 have been added, which are drawn to the elected group. Applicant's comments with regard to the relatedness of SEQ ID NO: 199, 210, 211 and 214 have been considered, and all 4 sequences have been examined herein.

Priority

Applicant is requested to update the status of priority applications in the specification. Several of the listed applications have either gone abandoned or been patented.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The assignment documents appear to list the addresses and residences of the inventors, but this is not sufficient.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Information Disclosure Statement

The Information disclosure statement, filed 2/13/02 has been entered and considered. An initialed copy of the PTO-1449 is enclosed with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification sets forth SEQ ID NO: 199, and SEQ ID NO: 210, 211 and 214 and how they was cloned.

The claims are drawn to methods of detecting ovarian cancer using "oligonucleotides that hybridize to SEQ ID NO: 199." The comments indicate Applicant also wishes the examiner to consider the claims with regard to SEQ ID NO: 210, 211 and 214 because they are related sequences. The specification does not provide written description of the genus of oligonucleotides encompassed by the claims. The four sequences range from a few hundred bases in length to a few thousand. There are no limits in the claims as to the lengths of the oligonucleotide probes, no limits on hybridization conditions, and no limits on the sequence identity required in order to be specific for SEQ ID NO: 199 (or any other sequence) such that their use would enable the detection of ovarian cancer. There is no indication of how one is to identify portions of SEQ ID NO: 199 or things that hybridize to it which would allow one to detect ovarian cancer. The genus of oligonucleotides required to practice the invention are only described by their ability to hybridize to the elected sequence.

By way of example, the examiner has provided various sequences that have stretches of complete identity to one or more of the sequences identified above. There is

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enormous variety in the types of sequences shown to have some stretches of complete, or high levels of identity. (complete identity would, by definition, hybridize) Sequences from human and mouse are present, and the sequences were derived from a wide variety of sources including:

 melanotic melanoma (Genbank BE385990 21 July 2000- having about 400 contiguous bases of SEQ ID NO: 214);

 anaplastic oligodendroma (Genbank AI936826 08 March 2000- the complement of which has about 200 contiguous bases to SEQ: 210 and 211);

 medulloblastoma (Genbank AW149665 03 November 1999- having about 150 contiguous nucleotides of SEQ: 210 and 211);

 well-differentiated endometrial adenocarcinoma (Genbank AW150789 03 November 1999- the complement of which has about 200 contiguous nucleotides of SEQ ID NO: 210); and

 infant brain (Genbank H06756 21 June 1995 having about 200 contiguous nucleotides of SEQ:199).

Are each of these partial sequences identical to portions of the elected sequences diagnostic for human ovarian cancer? These sequences are not described in the specification, nor are there indications of what probes to use, other than the full length sequence, that would be diagnostic for ovarian cancer. The claims as written do not require hybridization across the entire length of the sequence, nor do they require amplification of the entire sequence.

The courts have previously considered the written description requirement as applied to certain biotechnology patents, in which a gene material has only been defined by a statement of function or result and have held that such a statement did not adequately describe the claimed invention. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. In Eli Lilly, the court concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. Id. at 1567, 43 USPQ2d at 1405. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. Id.

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The court stated that an adequate written description of genetic material “requires a precise definition, such as by structure, formula, chemical name, or physical properties,” not a mere wish or plan for obtaining the claimed chemical invention.” Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. at 1568, 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

While the description of the ability of the claimed probe to bind to SEQ ID NO: 177 may describe the probe’s function, it does not describe the probe itself. The hybridization distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction.

The specification does not set forth any particular probes, other than the full length sequence, that hybridize to SEQ ID NO: 199, 210, 211 or 214 such that one could consider a representative number of species of the genus as being described. The specification merely sets forth a multitude of vague recitations as to what oligonucleotide probes could be, what lengths they could have, and what conditions might be useful. None of these satisfy the written description requirement.

The examiner has considered the disclosure in light of the Written Description Guidelines. The hybridization set out in the present claims is the only characteristic purportedly describing the claimed nucleotide sequences. The Guidelines do not provide that a nucleotide sequence may be defined only by its function. Describing a complicated molecule by means of a broad generic term (a nucleotide sequence) plus its function fails to distinguish it from other molecules that can perform the same function. Thus, in the absence of sequence information for its hybridization site, a nucleic acid described only by its ability to hybridize with another DNA fails to meet the requirements of § 112, ¶ 1.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz

11/13/02



MARY K. ZEMAN
PRIMARY EXAMINER

